510(k) Summary

JAN 31 2014

Submitter Name:	GMV Soluciones Globales Internet S.A.U.
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Date Prepared:	14 November 2013
Device Trade Name:	Radiance V2
Common Name	Radiation Treatment Planning Software
Classification Name, Number & Product Code:	Medical charged-particle radiation therapy system 21 CFR 892.5050 MUJ

Predicate Devices:

K112060	Radiance cleared 01/06/2012
K121653	INTRABEAM SYSTEM WITH INTRABEAM SPHERICAL APPLICATORS Cleared 12/27/2012
K102011	Eclipse Treatment Planning System Cleared 09/03/2010

Device Description and Statement of Intended Use

Radiance V2 is a treatment planning system, that is, a software program for planning and analysis of radiation therapy plans. Typically, a treatment plan is created by importing patient images obtained from a CT scanner, defining regions of interest either manually or semi-automatically, deciding on a treatment setup and objectives, optimizing the treatment parameters, comparing alternative plans to find the best compromise, computing the clinical dose distribution, approving the plan and exporting it.

Statement of Intended Use:

Radiance V2 is a software system intended for treatment planning and analysis of radiation therapy administered with devices suitable for intraoperative radiotherapy.

The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user.

The system functionality can be configured based on user needs.

The intended users of Radiance V2 shall be clinically qualified radiation therapy staff trained in using the system.

Summary of Technological Characteristics

The technological characteristics are essentially the same as those of the predicate.
All devices produce treatment plans with corresponding dose distributions computed using a three dimensional dosimetry engine. All devices have a function of electronic approval of treatment plans by trained and authorized staff, and export in DICOM format for commencing treatment or archiving.

Substantial Equivalence

From the standpoint of both functionality and workflow the Radiance V2 device is substantially equivalent to the identified predicates as follows:

- Within Radiance V2 and its predicates, Radiance and Eclipse, the user can adjust parameters to achieve a predicted outcome, rather than make a decision intra-operatively.
- Radiance V2 and its predicates Radiance and Eclipse are designed to analyze and plan radiation treatments in three dimensions for the purpose of treating patients with malignancies.
- Radiance V2 and its predicates Radiance and Eclipse provide treatment plans with estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by qualified medical personnel.
- Radiance V2 and its predicates Radiance and Eclipse use externally acquired medical images and user input to achieve the result.

The Radiance V2 dose distribution computation algorithm for the X-ray source of INTRA BEAM is equivalent to provided computation within INTRABEAM radiation treatment device

itself.
The added functionality of Radiance V2 versus Radiance is substantial equivalent to other marketed predicate devices and therefore there are no extra concerns on safety and efficacy of the proposed Radiance V2 device with respect to its predicates.

Non Clinical Data

Validation and Verification Testing carried out on the Radiance V2 indicates that it meets its predefined products requirements and requirements from the following product standards:

- IEC 61217 Radiotherapy equipment - Coordinates, movements and scales
- IEC 62083 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems

Clinical Data

The predecessor of Radiance V2 system, i.e., Radiance, has been tested clinically. This Clinical Study evaluated the effectiveness and repeatability of the planning process in IORT with Radiance in regard to the current modalities and the current uncertainties in regard to (manual) treatment planning. The changes in Radiance V2 (computation algorithms and beam modeling tool) do not modify basic functionality/workflow in which that study was performed. Therefore the Clinical Study conducted for Radiance and data collected can be safely extrapolated and is also valid for Radiance V2, moreover all new design features have been successfully validated ex-clinic.

Conclusion

The information discussed above demonstrates that the Radiance V2 device is substantially equivalent to the predicate device.

Declarations

- This summary includes only information that is also covered in the body of the 510(k).
- This summary does not contain any puffery or unsubstantiated labeling claims.
- This summary does not contain any raw data, i.e., contains only summary data.
- This summary does not contain any trade secret or confidential commercial information.
- This summary does not contain any patient identification information.

Summary of Technical Characteristics

Feature	Device Radiance V2	Radiance	Eclipse	INTRABEAM System with INTRABEAM Spherical Applicators
510(k) Number		K112060	K102011	K121653
Manufacturer	GMV Soluciones Globales Internet S.A.U.	GMV Aerospace and Defence S.A.	Varian Medical Systems, Inc.	Carl Zeiss Meditec AG
Classification # & Product Code	21 CFR 892.5050 MUJ	21 CFR 892.5050 MUJ	21 CFR 892.5050 MUJ	21 CFR 892.5900 JAD
Indication for use	Radiance V2 is a software system intended for treatment planning and analysis of intraoperative radiation therapy administered with devices suitable for intraoperative radiotherapy. The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user. The system functionality can	Radiance is a software system intended for treatment planning and analysis of intraoperative radiation therapy by means of electron beams. The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user. The system functionality can be configured based on user needs.	The Eclipse Treatment Planning System (Eclipse TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. Eclipse TPS is used to plan external beam irradiation with photon, electron and proton beams, as well as for internal irradiation (brachytherapy) treatments. In addition, the Eclipse Proton Eye algorithm is specifically indicated for planning proton treatment of neoplasms of the eye.	The INTRABEAM System is intended to be used for radiation therapy treatment.

	be configured based on user needs. The intended users of Radiance V2 shall be clinically qualified radiation therapy staff trained in using the system.	The intended users of Radiance shall be clinically qualified radiation therapy staff trained in using the system.		
System Design	Software only	Software only	Software only	Hardware and Software
Calculation for electrons	Dose distributions computed using a three dimensional dose engine. Pencil Beam computation and Monte Carlo Computation for electrons	Dose distributions computed using a three dimensional dose engine. Pencil Beam Computation	Same for electrons i.e. Pencil Beam computations and Monte Carlo Computation for electrons	Not applicable (X-ray device)
Calculation for photons	Dose Painting (Planning calculation interpolation of PDD measurements)	Not applicable	Not applicable	Calibration files for INTRABEAM: PDD scaled with the dose rate factor for MU computation of photons
Input	Externally acquired patient medical images and user input. Calibration files for INTRABEAM.	Same	Same	Calibration files for INTRABEAM: MU/Gy factor + additional factors
Output	Treatment plans with	Same for electrons	Same for electrons	Monitor units

	corresponding dose distributions			
Plan review and approval	Allows electronic approval of treatment plans by trained and authorized staff	Same	Same	None
Dose calculation algorithm confirmation	Algorithms confirmed for a wide variety of field geometries, treatment units, treatment setups and patient positions, including different dose grid resolution settings.	Same for electrons	Same for electrons	Same for MU computation
Beam modeling tool	Beam modeling of the treatment unit based on relative measurements and output factors.	None	Same	Not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 31, 2014

GMV Soluciones Globales Internet S.A.U.
% Ms. Debra Ferland
Official Correspondent for GMV
Qserve Group
P.O. Box 940
CHARLESTOWN NH 03603

Re: K133655
Trade/Device Name: Radiance V2
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: November 25, 2013
Received: December 4, 2013

Dear Ms. Ferland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133655

Device Name: Radiance V2

Indications For Use:

Radiance V2 is a software system intended for treatment planning and analysis of radiation therapy administered with devices suitable for intraoperative radiotherapy.

The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user.

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Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) _____K133655_____